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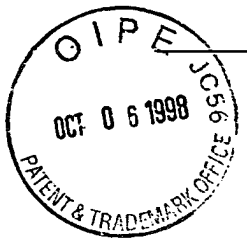

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Our Case No. 8998/3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

James A. Radosevich, Ph.D.

Serial No.: 09/040,485

Filing Date: March 17, 1998

For A GENE ENCODING A NOVEL MARKER FOR CANCER

Examiner:

Group Art Unit No.:

PETITION TO MAKE SPECIAL UNDER 37 CFR § 1.102(d)

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 CFR § 1.102(d) and under MPEP 708.02(X) and 1002.02 (c)(1)(h), applicant respectfully requests that the U.S. Patent and Trademark Office advance examination of the above-captioned patent application because the invention will advance the diagnosis, treatment, and prevention of cancer.

The invention relates a gene (*lab*) encoding a novel marker for cancer which is not restricted as a marker to previously defined histological classes of cancer. A petition fee as set forth in 37 C.F.R. § 1.17(i) is enclosed. Peptides of the marker antigen are useful to develop vaccines for treatment and prevention of cancer, and for

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the preparation of new, specific, monoclonal antibodies. These antibodies are for use in cancer chemotherapy.

REMARKS

Cancer[1] is a leading cause of death in men and women throughout the world. In the United States alone, over 1 million new cases are diagnosed each year, and over 0.5 million deaths are reported annually (Landis, *et al.*, 1998). Historically, tumors are grouped and treated, based in part by the tissues in which they arise, e.g.: breast cancer, colon cancer, and lung cancer, and the like. Yet, within lung cancer, for example, it is well recognized that these tumors are a very heterogeneous group of neoplasms. This is also true for tumors arising in other tissues. In part, because of this heterogeneity, there are complex and inconsistent classification schemes which are used for human tumors. Previous attempts to treat cancer have been hampered by : 1) the arbitrary classification of tumors arising within given tissues, and 2) by using microscopic methods based on how these tumors look (histological classification). Although existing classifications for various tumor types have some prognostic value, almost all of the classifications fail to predict responsiveness to treatments and likelihood of cure or disease course. Improved classification schemes based on the biological constitution of these neoplasms is required to significantly alter the survival statistics of humans who have cancer. One approach to solving these problems is provided by the marker of the present invention, which is a molecule specific to tumors.

[1] Terminology used herein is as follows: "cancer" is a malignant tumor, wherein a "tumor" is an abnormal mass of tissue, that need not be malignant. "neoplasm" is a form of new growth.

(A "marker" is defined herein as any property which can be used to distinguish cancer from normal tissues and from other disease states.) The markers' presence is a basis for classification.

The use of the tumor associated antigen (marker) of the present invention in a vaccine could prevent primary cancer occurrence, and could also provide a means to prevent recurrence of the disease.

An aspect of the invention is the use of *lab* DNA in the sense[2] expression mode for: 1) the marking of human tumors by nucleotide probes; 2) the detection of DNA and mRNA expression of *lab* in cells and tissues; 3) the transformation of cells into a glandular-like cell type; 4) the production of Lab antigen *in vivo* for immunization; 5) the *ex vivo* expression of Lab for immunization to produce antibodies; and 6) production of Lab *in vitro*. Use of an antisense molecule, e.g. by production of a mRNA or DNA strand in the reverse orientation to a sense molecule, to suppress the growth of *labyrinthin*-expressing (cancerous) cells is another aspect of the invention.

Another aspect of the invention is an amino acid sequence deduced from the protein coding region of the *lab* gene. Select regions of the sequence were found via immunological methods, to correspond and react to both naturally occurring (from cancer cells), chemically produced (synthetically produced peptides), and the expression of the cloned *lab* gene.

Another aspect of the invention is the use of the entire deduced amino acid sequence of Lab, peptides derived from Lab, or chemically produced (synthetic) Lab

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[2] The normal transcription of a DNA sequence which proceeds from the 3' to the 5' end to produce a mRNA strand from the sense strand of DNA, the mRNA being complementary to the DNA.

peptides, or any combination of these molecules, for use in the preparation of vaccines to prevent human cancers and/or to treat humans with cancer. For purposes of the present invention, "humans with cancer" are those persons who have the Lab antigen detected on their cells. These preparations may also be used to prevent patients from ever having these tumors prior to their first occurrence.

The use of the Lab protein or antigenic peptides derived therefrom in diagnostic assays for cancer is a way to monitor patients for the presence and amount of antibody that they have in their blood or other body fluids or tissue. This detection is not limited to cancers of a class or classes previously defined, but is useful for cancer cells that have the Lab marker antigen. The degree of seroconversion, as measured by techniques known to those of skill in the art [e.g. ELISA (Engvall and Perlmann, 1971)] may be used to monitor treatment effects.

Treatment with antisense molecules to *lab* or antibodies to Lab is an approach to treat patients who have Lab in, or on, their cancer cells.

REFERENCES

Engvall and Perlmann (1971) Immunochemistry 8:87.

Landis *et al.* (1998) Cancer Statistics CA 44:6.

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For the above reasons petitioner requests that the patent application captioned above be made special.

A check in the amount of the total fee under 37 CFR § 1.17(i) is attached. This amount is believed to be correct, but the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 23-1925.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and also that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or an patent issued therefrom.

Respectfully submitted,

Dated: October 6, 1998

Alice O. Martin
Registration No. 35,601
Attorney for Applicant

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4200